IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

In re GILEAD SCIENCES SECURITIES LITIGATION,

No. C 03-4999 MJJ

This Document Relates To:

ALL ACTIONS

ORDER GRANTING DEFENDANTS' 12(b)(6) MOTION TO DISMISS

INTRODUCTION

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003. Defendants seek an Order dismissing the Third Amended Class Action Complaint ("TAC") with prejudice under the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, Defendants' motion is **GRANTED** with leave to amend.

BACKGROUND

A. Factual History

The TAC is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003. The allegations in the TAC relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results. Viread is a groundbreaking

antiretroviral drug used to treat HIV/AIDS that was introduced in 2001. On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory levels in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter . . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory build-up: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers

return to more normal inventory levels and buying patterns." The form 10-Q also disclosed the existence of a July 29, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.[1]

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other materials on the uses of and the efficacy of an FDA-approved product that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling. Plaintiffs assert that the off-label marketing took three forms: 1) marketing to HIV patients co-infected with Hepatitis B virus ("HBV"); 2) marketing Viread as a first-line or initial therapy for HIV infection, and 3) marketing against Viread's safety profile.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October 2001. Later,

[1]Gilead initially made the FDA letter public on August 7, 2003.

employees allegedly were instructed at numerous regional and national sales meetings by Gilead executives "overtly and covertly," to use off-label information to aggressively promote and sell Viread.[2] At these meetings, employees allegedly would be provided off-label information such as updates on clinical trials of Viread in large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

According to the TAC, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was "extremely well-tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiffs allege that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter.

On March 21, 2002, Gilead responded stating that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the FDA issued a second letter notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations. In response to and in compliance with this letter, on November 7, 2003, defendant Martin wrote a correction letter to the conference's attendees.

---

[2]The TAC states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label. According to CW1, 85% to 95% of his Viread sales were a result of off-label marketing. Plaintiffs also allege that 85% to 90% of CW2's Viread sales were a result of off-label marketing.

Plaintiffs allege that Defendants provided so much off-label material and were so forceful in instructing off-label information that 75% to 95% of Viread sales arose from off-label promotion. According to the TAC, Gilead's second quarter 2003 domestic Viread sales were overstated by approximately $95 million due to off-label marketing.

B. Procedural History

On January 25, 2005, the Court dismissed Plaintiffs' Consolidated Amended Complaint ("CAC") with leave to amend ("the Order"). The Court found that Plaintiffs failed to "establish a connection between the company's off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading." (Order at 13:17-19.) The Court ruled that to establish such a connection, "Plaintiffs must allege that Gilead's off-label marketing scheme was a 'material fact' that needed to be disclosed to investors along with the 2003 second quarter sales reports." (Order at 13:19-21.) The Court also found that "Plaintiffs have not alleged any sales of Viread during the second quarter of 2003 were the result of improper off-label marketing activities." (Order at 13:22-23.) The Court noted that "Plaintiffs must allege facts that show a relationship between the off-label marketing of Viread, related sales of Viread, and the manner in which those sales affected Gilead's 2003 second quarter financial reports." (Order at 14:6-8.) Plaintiffs filed the TAC on March 11, 2005 in response to the Court's directives in the Order.

LEGAL STANDARDS

A. Rule 12(b)(6)

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of a cognizable legal theory or the pleading of insufficient facts under an adequate theory. *Robertson v. Dean Witter Reynolds, Inc.,* 749 F.2d 530, 533-34 (9th Cir. 1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to FRCP 12(b)(6), a court must take all of the material allegations in plaintiff's complaint as true, and construe them in the light most favorable to plaintiff. *Parks School of Business, Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Moreover, a complaint should not be dismissed unless a plaintiff could prove no set of facts in support of his claim that would entitle him to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents in the complaint.

Allarcom Pay Television, Ltd. v. General Instrument Corp., 69 F.3d 381, 385 (9th Cir. 1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F. Supp. 2d 1160, 1164 (N.D. Cal. 2001); *see also* Fed. R. Civ. P. 12(b). However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support plaintiff's claim. *See Pacific Gateway Exchange*, 169 F. Supp. 2d at 1164; *Branch v. Tunnell*, 14 F.3d 449, 44 (9th Cir. 1994), *cert. denied*, 512 U.S. 1219 (1997). Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Stay Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n.4 (1996), *cert denied*, 520 U.S. 1103 (1997). This rule precludes plaintiffs "from surviving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which their claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 705 (9th Cir. 1998).

B. Section 10(b) and Rule 10b-5

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

> (a) To employ any device, scheme, or artifice to defraud.
> (b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege (1) a misrepresentation or omission; (2) of material fact; (3) made with scienter; (4) on which the plaintiff justifiably relied; (5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184 F.3d 1059, 1063 (9th Cir. 1999). Additionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed. R. Civ. P. 9(b).

C. Section 20(a)

Section 20(a) of the Securities Exchange Act ("Exchange Act") provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

D. Private Securities Litigation Reform Act

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep. No. 104-369, 104th Cong., 1st Sess. at 32 (1995)) (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics Inc.*, 183 F.3d 970, 974 (9th

Cir. 1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court must dismiss the complaint. *See* 15 U.S.C. §78u-4(b)(1).

ANALYSIS

After the Court dismissed Plantiffs' CAC, Plaintiffs filed the TAC on March 11, 2005. The TAC alleges new facts, upon which Plaintiffs now primarily rely. Plaintiffs once again rely upon three theories to support their section 10(b) action: 1) Defendants' statements regarding wholesaler overstocking; 2) the financial impact of the off-label marketing scheme; and 3) Defendants' stock sales.[3]

Defendants move the Court to dismiss the TAC with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 9(b), and 12(b)(6) on several grounds. Defendants argue that: 1) Plaintiffs fail to adequately allege that Defendants illegally marketed Viread and that material illegal sales resulted from any such marketing; 2) Plaintiffs fail to allege fraud as to the wholesaler inventory estimate; and 3) Plaintiffs fail to adequately allege the element of loss causation.

A. Falsity and Scienter

To avoid having their action dismissed, Plaintiffs must "plead with particularity either the alleged misleading statements or scienter[.]" *In re Fritz Cos. Sec. Litig.*, 282 F. Supp. 2d 1105, 1112 (N.D. Cal 2003). The Ninth Circuit has articulated the rule as follows:

> Because falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, we have incorporated the dual pleading requirements of 15 U.S.C. §§ 78u-4(b)(1) and (b)(2) into a single inquiry. In considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), we must determine whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or deliberate recklessness made false or misleading statements to investors. Where pleadings are not sufficiently particularized or where, taken as a whole, they do not raise a "strong inference" that misleading statements were knowingly or deliberate recklessness made to investors, a private securities fraud complaint is properly dismissed under Rule 12(b)(6).

Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001) (citations and internal quotation marks omitted).

[3]As Plaintiffs have added no new allegations regarding wholesaler overstocking or stock sales, the Court need not address these allegations again. Thus, the Court will focus only upon the allegations involving the alleged off-label marketing scheme.

As the Court found in its previous Order, Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label marketing scheme.[4] (Order at 13:14-16.) When the allegations of CW1 and CW2 are considered in light of the FDA's letters to Gilead, it becomes apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme.

However, the Court previously found that Plaintiffs failed to establish a connection between the Defendants' off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading.[5] In order to remedy that deficiency, the TAC sheds further light upon the extent and impact of the alleged off-label marketing scheme. Specifically, the TAC relies upon the testimony of CW1 and CW2. According to CW1, 75% to 95% of all Viread sales in the United States were the result of off-label marketing. CW1 also alleges that 85% to 95% of his or her $3 million in Viread sales arose from off-label promotion. Similarly, the TAC states that approximately 85% to 90% of CW2's $25 to $35 million in Viread sales were a result of off-label marketing. As a result of off-label marketing, Plaintiffs conclude that Gilead's second quarter 2003 domestic Viread sales of $115.6 million were overstated by approximately $95.95 million. Plaintiffs also conclude that Gilead's third quarter 2003 domestic sales of $59.4 million were overstated by approximately $49.3 million.

Additionally, the TAC details the amount of Viread allegedly sold off-label. For example, according to the TAC, HIV patients co-infected with Hepatitis B initially began using Viread in the third quarter of 2002. At that time, only 55% of co-infected patients were allegedly using Viread. By the third quarter of 2003, 72.7% of co-infected patients surveyed were allegedly using Viread. Plaintiffs allege similar facts regarding the pervasiveness of patients using Viread as a first-line therapy. According to the TAC, Viread had an 11.2% market share as a first-line antiretroviral drug

---

[4]Defendants disagree with this ruling, and contend that "the specific marketing identified in the TAC was fully consistent with Viread's label and thus was completely proper." (Defendants' Motion to Dismiss TAC at 16:28-17:1.) The Court is unpersuaded. While the parties dispute the proper interpretation of the FDA's approval of Viread and Viread Package Labeling, the Court finds that this is a purely factual dispute, and hence it is not susceptible to resolution on a Rule 12(b)(6) motion.

[5]In other words, Plaintiffs must allege that Gilead's off-label marketing scheme was a "material fact" that needed to be disclosed to investors along with the 2003 second quarter sales reports. *See* 15 U.S.C. § 78u-4(b)(1)(B).

in the fourth quarter of 2001. (TAC at ¶161.) However, by the fourth quarter of 2003, Defendants had allegedly increased this market share to 27.45%. (TAC at ¶161.)

In order to connect these sales increases to Defendants' off-label marketing scheme, Plaintiffs allege that several doctors prescribed Viread for off-label purposes and received unsolicited off-label data from Defendants. For example, Plaintiffs allege that an AIDS-specialist treating between 2,000 and 2,500 AIDS patients prescribed Viread off-label and received unsolicited off-label data from Gilead. (TAC at ¶153.) Plaintiffs also allege that two infectious disease specialists in the Southeast United States both began to receive unsolicited advice on using Viread as a first line therapy from Gilead, and then both began using Viread as a first line therapy. (TAC at ¶160.)

After considering the totality of Plaintiffs' allegations, the Court has serious concerns regarding whether Plaintiffs have adequately alleged that the off-label marketing scheme affected Gilead's sales figures during the second and third quarter of 2003 in a "material" sense. To be certain, the allegations of CW1 and CW2, without more, are insufficient to establish "materiality" under the PSLRA.[6] Plaintiffs' remaining allegations generally involve the pervasiveness of the off-label marketing scheme, the percentage of patients that were allegedly prescribed Viread off-label, and the doctors that received off-label material from Gilead. Whether these allegations, when read in conjunction with the testimony of CW1 and CW2, sufficiently constitute a "material" omission is ultimately a close question. However, the Court need not decide that issue because even assuming that Plaintiffs have sufficiently alleged "materiality," there is no question that Plaintiffs have failed to adequately allege loss causation.

B. Loss Causation

Allegations of "loss causation" are a necessary element of a § 10(b) claim. *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627, 1631 (2005). The Supreme Court has recently clarified that merely alleging that a misrepresentation caused an inflated purchase price does not,

[6]CW1's "belief" that 75% to 95% of all sales of Viread in the United States were the result of off-label marketing is apparently only based upon CW1's own off-label Viread sales. The fact that a large majority of CW1's own Viread sales resulted from off-label marketing does not raise an inference that *all Viread sales* in the United states resulted from similar means. CW2's allegations are problematic for similar reasons.

without more, demonstrate loss causation. *Id.* at 1631-32. To "touch upon" an economic loss is insufficient; plaintiffs must demonstrate an actual "causal connection" between the defendant's material misrepresentation and the economic loss suffered. *Id*. at 1633. The Ninth Circuit has held that a plaintiff sufficiently pleads "loss causation" by alleging that there was a steep drop in defendants' stock price upon revelation by the defendants of previously undisclosed facts. *In re Daou Systems Inc*., 411 F.3d 1006, 1026 (9th Cir. 2005).

Defendants contend that Plaintiffs have failed to allege the element of loss causation. Defendants assert that Plaintiffs' loss causation allegations are flawed because Gilead disclosed the FDA's warning letter on August 7, 2003, but the drop in Gilead's share price did not occur until October 29, 2003. Defendants argue that the drop in the share price was a direct result of Gilead's October 28, 2003 statements, in which Gilead disclosed that its revenues for Viread in the third quarter of 2003 were less than in the previous quarter and that the company's earlier estimate of the level of second quarter inventory stocking by wholesalers had been too low. Thus, Defendants conclude that Plaintiffs have failed to establish a "causal connection" between the disclosure of the FDA's warning letter (containing the off-label marketing allegations) and the stock price drop.

Plaintiffs respond that the FDA warning letter caused Gilead's domestic sales – the overwhelming number of which were allegedly off-label – to substantially decline in comparison to what they would have been had the off-label marketing continued undiscovered. Plaintiffs assert that the sharp decline in Viread sales suggested that doctors – now alerted to Viread's safety problems and more limited approved uses - were less inclined to prescribe Viread. As a result, Plaintiffs contend that Gilead was unable to continue increasing prescriptions to new patients in line with growth rates of past quarters. Thus, Plaintiffs conclude that Gilead's dismal October 28 sales report, combined with the prior revelations of Gilead's off-label marketing by the FDA, caused Gilead's stock price to drop 12% on October 29.

The Court finds that Plaintiffs' allegations regarding loss causation are simply too attenuated to withstand scrutiny under *Dura*. As an initial matter, the Court notes that none of Gilead's disclosures on or around October 28 directly related in any way to off-label marketing. Rather, the only disclosures about Defendants' off-label marketing occurred when the FDA warning letter

became public on August 7, 2003 and again when Defendants filed their 10-Q on August 14, 2003. *See Dura*, 125 S. Ct. at 1634 ("The complaint's failure to claim that [ ] share price fell significantly after the truth became known suggests that the plaintiffs considered the allegation of purchase price inflation alone sufficient."). The record reflects that Gilead stock price actually rose following the public disclosure of the FDA letter and remained unchanged following the August 14 10-Q filing.

While Plaintiffs concede that the October 28 statements only discussed lower than expected sales numbers, they contend that the dismal financial numbers were a direct result of the disclosure of the off-label marketing scheme on August 7. Thus, Plaintiffs conclude they have sufficiently alleged a "causal connection" between the FDA letter and their losses. The Court disagrees. Plaintiffs contention relies upon the theory that doctors stopped prescribing Viread in such large quantities following the disclosure of the FDA letter, and that this change in prescribing patterns led to a drop in prescriptions that did not become apparent until the October earning release. However, this theory is problematic for a very simple reason – the Court is unable to find these allegations in the TAC. As a result, these allegations cannot serve as the basis for denying a motion to dismiss.[7]

Moreover, Plaintiffs contend that the absence of a stock price drop following the disclosure of the FDA letter was a result of investors not suspecting "that almost all of Defendants' domestic sales depended on off-label marketing." (Plaintiffs' Opposition to Motion to Dismiss TAC at 27:20-21.) However, this argument is flawed because the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme. Neither Defendants, the FDA, nor a third party ever disclosed such information to the investing public.

Thus, when the TAC is analyzed in light of *Dura*, it is evident that Plaintiffs have not adequately alleged proximate causation and economic loss with respect to Gilead's alleged off-label marketing scheme. To be certain, Plaintiffs do not allege that a price drop immediately accompanied the disclosure of the FDA warning letter, and hence the Court is left to speculate as to what portion of the eventual loss, if any, should be attributed to the disclosure or whether the loss was caused by other factors. "But it should not prove burdensome for a plaintiff who has suffered an economic loss

[7]In any event, this theory is in direct conflict with Gilead's actual disclosures on October 28, 2003, informing the market that new and total prescriptions increased as compared to the second quarter and as compared to the third quarter of the prior year.

to provide defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura*, 125 S. Ct. at 1634. As in *Dura*, Plaintiffs have failed to make such an indication in the TAC. Accordingly, the Court finds that Plaintiffs have failed to adequately plead loss causation.

C. RULE 20(a) LIABILITY

Section 20(a) of the Securities Exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

Here, Plaintiffs assert that the individual Defendants are liable under this section because of an underlying violation of section 10(b). However, because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the section 20(a) claims must be dismissed as well.

D. DISMISSAL WITHOUT PREJUDICE

Leave to amend under Federal Rule of Civil Procedure 15 should be liberally granted. "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital v. Aspeon Inc.*, 316 F.3d 1048, 1053 (9th Cir. 2003) (error to refuse leave to amend in a securities fraud case to allow plaintiff to plead scienter). Here, the Court notes that after the TAC was filed, *Dura* changed Ninth Circuit law with respect to the pleading of loss causation. Leave to amend is warranted where there has been an intervening change in the law. *See Wilcox v. First Interstate Bank, N.A.*, 815 F.2d 522, 530 (9th Cir. 1987). Accordingly, the Court dismisses the TAC without prejudice. The Plaintiffs should file an amended complaint within thirty (30) days from the date of this Order.

CONCLUSION

In light of the heightened pleading standards of the PSLRA and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court **GRANTS** Defendants' 12(b)(6) motion to dismiss the TAC without prejudice.

///

///

///

///

IT IS SO ORDERED.

Dated: October_11_, 2005

MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE